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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/542,958	01/30/2007	William R. Jacobs JR.	96700/1031	2060
1912	7590	04/03/2008	EXAMINER	
AMSTER, ROTHSTEIN & EBENSTEIN LLP			SWARTZ, RODNEY P	
90 PARK AVENUE			ART UNIT	PAPER NUMBER
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**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b> 10/542,958	<b>Applicant(s)</b> JACOBS ET AL.
	<b>Examiner</b> Rodney P. Swartz, Ph.D.	<b>Art Unit</b> 1645

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If no period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

1) Responsive to communication(s) filed on 21 July 2005.  
 2a) This action is FINAL.      2b) This action is non-final.  
 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

4) Claim(s) 1,5,8,10,12,13,16-19,22-25,28,30,32,38,39 and 41 is/are pending in the application.  
 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.  
 5) Claim(s) \_\_\_\_\_ is/are allowed.  
 6) Claim(s) 1,5,8,10,12,13,16-19,22-25,28,30,32,38,39 and 41 is/are rejected.  
 7) Claim(s) \_\_\_\_\_ is/are objected to.  
 8) Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

9) The specification is objected to by the Examiner.  
 10) The drawing(s) filed on 21 July 2005 is/are: a) accepted or b) objected to by the Examiner.  
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).  
 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
 a) All    b) Some \* c) None of:  
 1. Certified copies of the priority documents have been received.  
 2. Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.  
 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

1) Notice of References Cited (PTO-892)  
 2) Notice of Draftsperson's Patent Drawing Review (PTO-646)  
 3) Information Disclosure Statement(s) (PTO/SB/08)  
 Paper No(s)/Mail Date 7/06.      4) Interview Summary (PTO-413)  
 Paper No(s)/Mail Date \_\_\_\_\_.  
 5) Notice of Informal Patent Application  
 6) Other: \_\_\_\_\_

**DETAILED ACTION**

1. Applicants' Preliminary Amendment, received 21 July 2005, is acknowledged.

It is noted by the examiner that not all of the claims are listed properly, i.e., "original" or previously presented", etc.

Claims 2, 3, 4, 6, 7, 9, 11, 14, 15, 20, 21, 26, 27, 29, 31, 33, 34, 35, 36, 37, 40, and 42-86 have been canceled.

2. Claims 1, 5, 8, 10, 12, 13, 16-19, 22-25, 28, 30, 32, 38, 39 and 41 are pending and under consideration.

**Specification**

3. The disclosure is objected to because of the following informalities:

Page 16, line 6, lists the data in Figure 6B as solid triangles and solid circles, there are no solid circles in Figure 6B; line 27, lists the data in Figure 8C as open circles and open circles, the figure contains solid circles and open circles.

Page 17, the Description of Fig. 10 lists panels as a, b, c, d, e, and f, but the figure is labeled A, B, C, D, E, F.

Page 17, the Description of Fig. 11, lists panels as a, b, c, d, e, and f, but the figure is labeled A, B, C, D, E, F.

Page 18, the Description of Fig. 14 lists data as a large open box and a small open box, but the figure shows open box and solid box.

Page 19, the Description of Fig. 15 lists data as solid box, solid diamond, and solid circle for Panel A, but the panel shows colid box, open diamond, and open circle.

Page 20, the Description of Fig. 22 lists panels as a, b, c, d, e, f, g, h, and i, but the figure is labeled A, B, C, D, E, F, G, H, I.

Page 20, the Description of Fig. 23 lists panels as a, b, c, d, and e, but the figure is labeled A, B, C, D, E.

Page 21, the Description of Fig. 24 lists panels as a, b, c, d, e, and f, but the figure is labeled A, B, C, D, E, F.

Page 21, the Description of Fig. 25 lists panels as a, b, c, d, e, and f, but the figure is labeled A, B, C, D, E, F.

Page 47, line 14, "FIG. 10a" should be "FIG. 10A"; line 22, "FIG. 10b" should be "FIG. 10B".

Page 48, line 1, "FIG. 10c" should be "FIG. 10C"; line 4, "FIG. 10d" should be "FIG. 10D"; line 5, "FIG. 10e" should be "FIG. 10E"; line 7, "FIG. 11a,b" should be "FIG. 11A,B"; line 12, "FIG. 11c" should be "FIG. 11C"; line 16, "FIG. 11d" should be "FIG. 11D".

Page 49, line 10, "FIG. 11e,f" should be "FIG. 11E,F".

Page 53, lines 4 and 9, "FIG. 4B-D" should be "FIG. 4b-d"; line 11, "FIG. 5D-F" should be "FIG. 5d-f"; line 22, "FIG. 5G-I" should be "FIG. 5g-I".

Page 54, line 11, "Fig. 3F-G" should be "FIG.3f-g"; line 12, "FIG. 3E" should be "FIG. 3e"; line 17, "FIG. 3D" should be "FIG. 3d"; line 19, "FIG. 3A-C" should be "Fig. 3a-c".

Page 68, line 26, "FIG. 22a" should be "FIG. 22A"; line 29, "FIG. 22b" should be "FIG. 22B"; line 31, "FIG. 22c" should be "FIG. 22C".

Page 69, line 22, "FIG. 22e" should be "FIG. 22E"; line 23, "FIG. 22f" should be "FIG. 22F"; line 26, "FIG. 22g" should be "FIG. 22G"; line 30, "FIG. 22h" should be "FIG. 22H"; line 34, "FIG. 22i" should be "FIG. 22I".

Page 70, line 15, "FIG. 23a,b" should be "FIG. 23A,B"; line 22, "FIG. 23c,d" should be "FIG. 23C,D".

Page 71, line 15, "FIG.24a,b" should be "FIG. 24A,B"; line 19, "FIG. 24c" should be "FIG. 24C"; line 3, "FIG. 25a,d" should be "FIG. 25A,D"; line 32, "FIG. 25c,f" should be "FIG. 25C,F".

Page 72, line 15, "FIG. 24d,e" should be "FIG. 24D,E"; line 22, "FIG. 24f" should be "FIG. 24F".

Appropriate correction is required.

#### **Drawings**

4. Figure 1 is objected to because there is no panel labeled "a", and the quality of the blots in panels b and c are show little if any data.
5. Figure 2 is objected to because the quality is so poor that writing and symbols cannot be distinguished.
6. Figure 3 is objected to because the quality is so poor that writing and symbols cannot be distinguished.
7. Figure 4 is objected to because the quality is so poor that writing and symbols cannot be distinguished, and the ordinate labels are mingled with the graphs.
8. Figure 5 is objected to because the quality is so poor that panel labels and details of the micrographs cannot be distinguished.
9. Figure 6B is objected to because there is no solid triangle as described in the Brief Description.
10. Figure 18B is objected to because the quality is so poor that symbols cannot be distinguished.

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11. Figure 25 is objected to because the quality is so poor that panel labels and details of the micrographs cannot be distinguished.
12. Corrected drawing sheets in compliance with 37 CFR 1.121(d) are required in reply to the Office action to avoid abandonment of the application. Any amended replacement drawing sheet should include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being amended. The figure or figure number of an amended drawing should not be labeled as "amended." If a drawing figure is to be canceled, the appropriate figure must be removed from the replacement sheet, and where necessary, the remaining figures must be renumbered and appropriate changes made to the brief description of the several views of the drawings for consistency. Additional replacement sheets may be necessary to show the renumbering of the remaining figures. Each drawing sheet submitted after the filing date of an application must be labeled in the top margin as either "Replacement Sheet" or "New Sheet" pursuant to 37 CFR 1.121(d). If the changes are not accepted by the examiner, the applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

#### **Claim Rejections - 35 USC § 112**

13. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

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14. Claims 1, 5, 8, 10, 12 13, 16-19, 22-25, 28, 30, 32, 38, 39, and 41 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The claims are drawn to a method of treating a mammal which does not have combined immune deficiency, but is deficient in CD4<sup>+</sup> lymphocytes, by inoculating the mammal with attenuated mycobacterium.

It is unclear what the claim is drawn to because there is no recitation of any disease, disorder, or condition for which the animal is being treated. Therefore, the metes and bounds of the claimed invention is indefinite.

### **Conclusion**

15. No claims are allowed.

16. Any inquiry concerning this communication or earlier communications from the Examiner should be directed to Rodney P. Swartz, Ph.D., Art Unit 1645, whose telephone number is (571) 272-0865. The examiner can normally be reached on Monday through Wednesday from 9:00 AM to 7:30 PM EST. Thursday is the examiner's work at home day.

If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's Supervisor, Shannon Foley, can be reached on (571)272-0898.

The fax phone number for the organization where this application or proceeding is assigned is (571) 273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR

system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

/Rodney P. Swartz, Ph.D./

Primary Examiner, Art Unit 1645

March 30, 2008